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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/423,037	02/22/2000	DAVID MICHAEL HEERY	PM264015	6259

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FISH & NEAVE IP GROUP  
ROPES & GRAY LLP  
ONE INTERNATIONAL PLACE  
BOSTON, MA 02110-2624

EXAMINER

MCKELVEY, TERRY ALAN

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 06/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/423,037

Applicant(s)

HEERY ET AL

Examiner

Terry A. McKelvey

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 3-23 is/are pending in the application.
- 4a) Of the above claim(s) 5, 6 and 14-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4, 7-13 and 23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10/29/99 *(copy was missing from file)* *signed*
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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**DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All objections and rejections not repeated in the instant Action have been withdrawn due to applicant's response to the previous Action.

***Election/Restrictions***

Claims 5-6 and 14-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/13/01.

Applicant indicates in the response filed 12/23/02 that claim 1 is a generic claim linking elected and non-elected species. The arguments based upon this assertion are not persuasive because claim 1 is a generic claim, and claims 5-6 are drawn to non-elected species encompassed by claim 1, but claim 1 is not a linking claim because by definition linking claims link otherwise properly divisible inventions, i.e., distinct and/or independent inventions that would be in separate groups in the restriction requirement. See MPEP 809.03. That

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is not the case here. But, as per the election of species requirement mailed 9/11/01, page 4, second paragraph, upon allowance of a generic claim, applicant is entitled to consideration of claims to additional species as per that paragraph. As the instant action shows, none of the claims are allowable, including the generic claims. The applicant also indicates that the burden is on the Examiner to examine these generic claims throughout their scope, together with any claims dependent thereon drawn to non-elected species or inventions, rather than for Applicants to limit the scope of the generic claims to conform to the scope of any species or inventions listed in a restriction requirement. This statement is incorrect. Non-elected inventions and species are withdrawn from consideration and thus are not examined at all unless and until they are rejoined or considered because of the allowability of the elected claims. That is the purpose of restriction and election of species, to remove from consideration non-elected inventions and species based upon specific criteria that was not traversed in the response to the restriction requirement. The allowability of elected generic claims is determined throughout its scope.

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***Claim Objections***

Claims 1, 3-4, 7-13, and 23 are objected to because of the following informalities: improper use of brackets in claim 1, improper strike-through of a single letter "a" in claim 1 (it is difficult to determine whether it is struck-through; double-brackets should be used to delete such single letters. Also, claim 8 uses improper brackets for indicating deletion. Appropriate correction of all improper amendment formats, including any not otherwise note is required. (Applicant should review the entire amendment for such improper amendments and fix them.)

***Claim Rejections - 35 USC § 112***

Claims 1, 3-4, 7-13, and 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new rejection necessitated by the applicant's amendment to the claims filed 3/28/05.

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The introduction of "provided that a fragment that includes residues 624-1287 of TIF-2 is excluded" into the claims amended 3/28/05 resulted in the introduction of new matter because this limitation to the claimed method is not described or present in the specification as filed and this particular TIF-2 fragment in the context of the claimed invention is not set forth in the specification as filed as being in the prior art. For example, if this fragment had been explicitly described in the specification as filed as being in the prior art in the context of the claimed invention, then it could have been excluded with a negative proviso such as in the instant amendment without introducing new matter. However, that is not the case in the actual instant specification. No specific support for this amendment is noted by the applicant, except "Support of the subject matter of this new claim is found throughout the application." This is not the case for the reasons described above. The applicants did argue the following, with regard to the appropriateness of the new limitation to the claims.

Applicants argue that narrowing claim 1 by excluding the TIF-2 fragment including 624-1287 from the claimed nuclear protein fragment is appropriate based upon the proposition that if an applicant has a genus and some species, he or she ought to

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be able to claim the genus excluding the disclosed species, and that the only inquiry is whether the original disclosure satisfied 112, first paragraph, for the limited genus later claimed. The applicants argue that their disclosure has satisfied the requirements under 112, first paragraph, for the entire genus of nuclear fragments comprising a signature motif, exclusive of the TIF-2 fragment including 624-1287. These arguments are not persuasive in overcoming the instant rejection because the specification as filed did not disclose the species that the applicants are trying to exclude. So, the requirements that the applicants themselves are arguing with regard to In re Johnson are not even met. The specification as filed simply fails to discuss TIF-2 fragment including 624-1287 at all, let alone in the context of the claimed method. Since the species of TIF-2 fragment including 624-1287 is not disclosed in the context of the claimed invention, it cannot be excluded from the genus of the claimed invention. Therefore, the applicants have not satisfied the requirements under 112, first paragraph for the limited genus now claimed.

#### **Conclusion**

No claims are allowed.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does



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submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and


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history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Terry A. McKelvey whose telephone number is (571) 272-0775. The examiner can normally be reached on Monday through Friday, except for Wednesdays, from about 7:30 AM to about 6:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.



**Terry A. McKelvey, Ph.D.**  
**Primary Examiner**  
**Art Unit 1636**

June 12, 2005